Testimony Presented to the Public Health Committee of the Connecticut General Assembly

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S.B. 442 An Act Prohibiting Predatory Pricing of Pharmaceuticals and S.B. 445 An Act Concerning Pharmaceutical Price Transparency and Disclosure

Good afternoon Senator Gerratana, Senator Somers, Representative Steinberg, Senator Kennedy, Senator Logan, Representative Luxenberg, Representative Srinivasan, members of the Public Health Committee.

I'm Paul Pescatello, Senior Counsel and Executive Director of the Connecticut Bioscience Growth Council.

I am also President/CEO of the New England Biotechnology Association and Chair of We Work for Health Connecticut.

The Connecticut Bioscience Growth Council is a committee of the Connecticut Business and Industry Association's biotech and biopharma members.

The Bioscience Growth Council was formed as a means to foster collaboration both among Connecticut biotech and biopharma companies themselves and, just as importantly, with our state. As you know, Connecticut – this General Assembly – has chosen wisely to invest in the life sciences as a foundation for Connecticut's 21st century economy and as a means to create a broad spectrum of jobs.

I am here today to speak on S.B. 442, An Act Prohibiting Predatory Pricing of Pharmaceuticals, and S.B. 445, An Act Concerning Pharmaceutical Price Transparency and Disclosure.

The issue is the cost of healthcare, not just drug prices.

Bioscience Growth Council members believe this legislation focuses on one relatively small component of the healthcare equation. Consumer and patients would be better served if the legislation took a broader approach that addressed the genuine issue at hand – the cost of healthcare.

Viewed in the context of overall healthcare spending, prescription medicines comprise a comparatively small share of 10 to 15%. And prescription medicines' share of the healthcare dollar has remained remarkably consistent (at 10 to 15%) since World War II. To rein in healthcare spending it is critical that we assess the value and efficiency of healthcare delivery as provided by the other players in the healthcare system who comprise the other 85 to 90%.

It is instructive to note that in the clinical trial process for medical devices, where the aim is to implant, for example, an artificial knee in similarly situated patients across the country, the one constant and most transparent cost factor is the cost of the medications used in the surgical procedure. Hospital, physician and other costs, on the other hand, vary widely.

New medicine research and development reduces healthcare costs.

S.B. 442 and 445 appear to be rooted in a (misguided) belief that prescription medicines are the sole cause of healthcare cost inflation. In fact, medicines add value and lower overall healthcare costs. Often, their cost is less than what they replace.

Patients cured of melanoma with an immunotherapy medicine, or cured of Hepatitis-C with anti-viral medication, or whose disease never manifests itself owing to LDL (bad) cholesterol-lowering drugs, or whose HIV medications allow them to remain in the workforce for decades after diagnosis, cost the healthcare system far less than the same patients treated without the benefit of these innovative biopharmaceuticals.

Cutting-edge medicines are sometimes labeled "expensive," but, in fact, are bargains compared to the disease management costs, hospitalizations, outpatient and in-home nursing care they replace.

Egregious price increases are a result of defects in federal regulation, not state policy.

The focus on drug costs and the desire "to do something about them" is, not surprisingly, driven in part by a few egregious examples of manufacturers using monopoly power to raise prices. To describe these examples as "a few" is a misnomer—"miniscule number" would be more accurate. There are over 1,200 prescription medicines, making the handful of extraordinary pricing events a tiny fraction of the overall market.

The monopoly power that has allowed steep price increases is a function of—and is rooted in—federal regulation. The small number of medicines whose prices have risen dramatically have all been "off patent." That is, the patent of the company which discovered and developed the drug has expired. This means other manufacturers have free access to the drug's "recipe" and can make generic or biosimilar copies. Unfortunately, the federal Food and Drug Administration takes three years to process applications to produce generic drugs. Dramatic price increases wouldn't be possible if the market was allowed to work more efficiently and generic competitors were able to enter the market in a timely manner.

Consider this: a drug formula is known and well documented, an applicant has an FDA-approved facility ready to manufacture the generic drug, yet the FDA takes three years to approve the cheaper generic. Rather than speeding the workings of the market and promoting price competition, the unnecessarily long FDA review process facilitates market manipulation. This is a federal problem to be addressed at the federal level.

The huge costs of successful and unsuccessful research and development.

S.B. 442 and 445 should reflect an understanding and appreciation of how biopharma companies determine prices for their innovations. It is a highly complex matter that varies research project to research project. A new medicine price reflects manufacturing costs – the cost of sourcing ingredients, forming them together into pills, injectables or infusions and delivering them to pharmacies – but more importantly the research and development that made manufacturing possible.

It takes 12 years and \$2.6 billion to bring a new medicine from research concept through clinical trials and FDA approval to pharmacy shelves. Most new medicine projects fail to result in an FDA-approved new medicine. This research is valuable and informs future research – insights and lessons learned from "failed" research often is the foundation for new research and development programs – but if the private sector is to continue to make such huge investments it must be confident that it can recoup the costs of unsuccessful research and development through the few research and development programs that are successful. This incentive is critical because biopharma management, employees and investors are constantly assessing whether other much less risky investments, though of much less value to society, like over-the-counter cold medications or "cosmeceuticals," make more financial sense.

Opaque and confusing PBM and wholesale drug purchasing system.

There are many junctures in our healthcare system where inefficiencies occur and that are worthy of attention. Pharmacy benefit managers and drug wholesalers, for example, siphon off revenue in a system that has become unnecessarily complex and opaque, and sometimes antithetical to lowering costs to patients.

We should not slow innovation.

But perhaps the most important concept for S.B. 442 and 445 to reflect is an understanding that biopharma research and development is *not* an economic drag on healthcare costs. As stated earlier, biopharma research and development actually lowers long-term healthcare costs.

In a similar vein, we in Connecticut have made a substantial investment in life sciences innovation. We describe ourselves as "the life sciences state" and view the industry as a means to rebuild our economy and create high paying jobs and careers for our citizens. S.B. 442 and 445 should not weigh down this important industry with additional regulatory burdens, and thereby slow innovation, job creation, and the development of treatments and cures for patients.

I would be happy to answer any questions you may have or expand upon any points made in my testimony.

Thank you.